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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,368	10/26/2001	James P. Hoeffler	IVGN 274.2	2504

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EXAMINER	
COOK, LISA V	
ART UNIT	PAPER NUMBER
1641	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/035,368	HOEFFLER ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,21-24,48-50,61,64 and 68-87* is/are pending in the application.

4a) Of the above claim(s) *21-24,48-50,61,64,68-70,83 and 85-87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,71-82 and 84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *18, 21-24, 48-50, 61, 64, and 68-87* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Non-Compliant Amendment

1. The amendment filed 2/26/07 inadvertently listed claim 80 as NEW. This error has been corrected by the Examiner. The appropriate status indicator is (Currently Amended).

Amendment Entry

2. Applicants' response to the Office Action mailed 10/25/06 is acknowledged. In the amendment filed therein claims 61-82, and 84 were modified. Currently, claims 18, 21-24, 48-50, 61, 64, and 68-87 are subject to Species Restriction and Election Requirement. Claims 21-24, 48-50, 61, 64, 68-70, 83, and 85-87 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as claims drawn to a non-elected invention. Claims 18, 71-82 and 84 are currently under examination.

3. Rejections and/or objections of record not reiterated below have been withdrawn.

NEW GROUNDS OF REJECTIONS

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 18 and 71 are rejected under 35 U.S.C. 103(a) as being obvious over Brott et al. (Proceedings of the National Academy of Science, USA, Vol.88, pages 755-759, February 1991) in view of Piehler et al. (SPIE, 1995, Vol.2504 pages 185-194).

Brott et al. disclose the evaluation of protein binding patterns (molecular interactions) in cell lysates of GTPase-activating protein (GAP) and two Src Kinases. The researches found that GAP may have a role din mediating normal functions of $p60^{c\text{-}src}$ as well as oncongenic activities of $p60^{v\text{-}src}$. See abstract.

In particular, two different cell lines (cell populations) were employed. The SR-3Yi and NY5H were lysed and the cell lysates incubated with an appropriate antibody. See page 755 2nd - Materials and Methods and page 756 1st column – Antibodies. The protein binding patterns were compared and the differential expression of GAP was analyzed. See figures 1, 2, 3, and 4.

The data presented suggests that normal p60c-src and oncogenic p60v-src are associated with complexes containing GAP in cell lysates. This interaction may contribute to subversion of normal growth control mechanisms. See page 758 2bd column 1st paragraph and last paragraph.

Brott et al. differ from the instant invention in not specifically teaching the use of a microarray comprising antibodies.

However, Piehler et al. teach methods to detect multiple analyte proteins in an antibody array (microarray comprising antibodies) system. The method utilizes a plurality of cross-reacting antibody species to selectively generate binding patterns (affinity-characterization). See abstract, figure 5 and figure 6, for example. The antibody arrays can differentiate between various analytes. See page 192 last paragraph. They also provide a possibility for a systematical tailoring of an antibody array from a library for a specific application. See page 194.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use microarrays as taught by Piehler et al. in the method of Brott et al. because Piehler et al. taught that the antibody arrays can differentiate between various analytes. See page 192 last paragraph. They also provide a possibility for a systematical tailoring of an antibody array from a library for a specific application. See page 194.

One of ordinary skill in the art would have been motivated to employ microarrays in order to conduct multiple antibody-analyte simultaneously.

II. Claims 72-75, 77, and 80-82 are rejected under 35 U.S.C. 103(a) as being obvious over Brott et al. (Proceedings of the National Academy of Science, USA, Vol.88, pages 755-759, February 1991) in view of Piehler et al. (SPIE, 1995, Vol.2504 pages 185-194) and further in view of Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991).

Please see Brott et al. (Proceedings of the National Academy of Science, USA, Vol.88, pages 755-759, February 1991) in view of Piehler et al. (SPIE, 1995, Vol.2504 pages 185-194) as set forth above.

Brott et al. (Proceedings of the National Academy of Science, USA, Vol.88, pages 755-759, February 1991) in view of Piehler et al. (SPIE, 1995, Vol.2504 pages 185-194) differ from the instant invention in not specifically teaching multiple antigens and antibody preparations.

However, Ekins et al. teach method to detect proteins via multianalyte microspot immunoassays. An array of antibodies (device comprising multiple immobilized agents for protein detection such as antibodies) is exposed to proteins to monitor the expression and properties of a large number of proteins. See abstract and figures 4 and 5.

The detection procedure can be evaluated with a radioactive isotopes (i.e. I^{125}), an enzyme, chemiluminescent label, or fluorescence label. See page 1960. In one embodiment dual microspot assay devices are compared. See page 1961 figure 8 for example. The microarrays taught by Ekins can measure tens, hundreds, or thousands of analytes. Thus the array may comprising 106 Ab (antibody) micro-spots each directed against a different analyte See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the protein patterning procedures as taught by Brott et al. (Proceedings of the National Academy of Science, USA, Vol.88, pages 755-759, February 1991) in view of Piehler et al. (SPIE, 1995, Vol.2504 pages 185-194) with multiple antigens and antibodies as exemplified by Ekins et al. because Ekins et al. taught that antibody arrays can be configured to measure tens, hundreds, or thousands of analytes. See abstract.

Absent evidence to the contrary the adjustment of the prior art to employ multiple antigens and antibodies is deemed routine. It has been held that the provision of adjustability, where need, involves only routine skill in the art. *In re Stevens*, 101 USPQ 284 (CCPA 1954).

One of ordinary skill in the art would have been motivated to utilize multiple antigens and antibodies in order to generate more data sets for analysis.

III. Claims 76, 78-79 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brott et al. (Proceedings of the National Academy of Science, USA, Vol.88, pages 755-759, February 1991) in view of Piehler et al. (SPIE, 1995, Vol.2504 pages 185-194) and in further view of James F. Cupo (Journal of Chromatography, 569, 1991, 389-40).

Please see Brott et al. (Proceedings of the National Academy of Science, USA, Vol.88, pages 755-759, February 1991) in view of Piehler et al. (SPIE, 1995, Vol.2504 pages 185-194) as set forth above.

Brott et al. (Proceedings of the National Academy of Science, USA, Vol.88, pages 755-759, February 1991) in view of Piehler et al. (SPIE, 1995, Vol.2504 pages 185-194) differ from the instant invention in not teaching protein expression pattern evaluation in cancer diseases or virus cell lines (like T cells).

However, Cupo teaches a two-dimensional polyacrylamide gel electrophoresis procedure to measure matrix proteins. The proteins are tissue-type specific and can reflect changes in the state of differentiation of a cell. The method can further distinguish between a diseased cell and a normal cell. The disease states include various cancers, autoimmune disease, and adenoviral infection. See abstract.

The method is quick and efficient employing the appropriate antibodies to the protein of interest. Page 403, 1st paragraph. Protein patterning in T lymphocytes (T cells) is outlined on page 400. The method is used to detect early stages of viral infection because a virus must replicate cellular components associated with the nuclear matrix. Such changes are evident in protein patterning analysis. See page 403 – 4.3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use protein patterning procedures to evaluate cancer diseases or virus cell lines (like T cells) and further allowing for cellular replication distinctions (differential development) via polyacrylamide as taught by Cupo in the protein procedure of Brott et al. (Proceedings of the National Academy of Science, USA, Vol.88, pages 755-759, February 1991) in view of Piehler et al. (SPIE, 1995, Vol.2504 pages 185-194) because Cupo taught that two-dimensional gels can determine tissue-type specific differences in nuclear matrix proteins and the differences between normal and carcinogenic cells. See page 402 - 4.2 Further these proteins play an important role in cells.

Utilization of the proteins can lead to the development of diagnostic agents to detect various diseased conditions of the cell and organism (including cancer and viruses). Cupo page 404.

Response to Arguments

Applicant's argument's filed 2/26/07 against the previously cited art is MOOT because new claims and rejections have been presented in the instant office action.

5. For reasons aforementioned, no claims are allowed.

Remarks

6. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Fields et al. (U.S. Patent #5,283,173) disclosed systems to measure protein-protein interactions.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week.

In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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5/3/07

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